

16. (New) A substantially purified nucleic acid molecule consisting of a fragment from about 30 to about 300 nucleotides residues, wherein said fragment exhibits complete complementarity to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.
17. (New) The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule further comprises a microsatellite sequence.
18. (New) The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.
19. (New) The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.
20. (New) The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule further comprises a bacterial ORI site.
21. (New) The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule has a promoter or partial promoter region.
22. (New) The substantially purified nucleic acid molecule according to claim 21, wherein said promoter region comprises a CAAT *cis* element and a TATA *cis* element and an additional *cis* element.

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### Remarks

Applicants have canceled claims 8-15, added claims 16-22 and amended claims 1 and 4. Following entry of this amendment, claims 1-7 and 16-22 will be pending. Claims 16-22 are supported by originally filed claims 1-7. No new matter is added by the amendments.

**I. Specification.**

Applicants have amended the specification to remove browser executable code in compliance with MPEP 608.01(b). In view of the foregoing, Applicants respectfully request withdrawal of the objection of record.

**II. 35 U.S.C. § 112 second paragraph**

**Claims 1-7 are rejected under 35 U.S.C. § 112 second paragraph**

The Examiner has rejected claims 1 and 4 as being vague and indefinite for the recitation of "complement." The Examiner further asserts that it is not clear whether the term "complement" refers to the first nucleic acid or the second nucleic acid. In addition the Examiner asserts that the term "substantially purified" in claims 1-7 is not clearly defined.

Applicants respectfully disagree. Claims are not read in a vacuum and are to be interpreted in light of the specification. *In re Okuzawa*, 537 F.2d 545, 548, 190 U.S.P.Q. 464, 466 (CCPA 1976). The specification at page 12, line 25 to page 13, line 5, address the meaning of "substantially purified," and the specification at page 14, lines 4-12 addresses the meaning of "complement" such that one skilled in the art would be appraised of that which is claimed. In addressing the requirement of 35 U.S.C. 112 second paragraph the Court of Appeals for the Federal Circuit stated if "claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Shatterproof Glass v. Libbey Owens Ford, Co.*, 758 F.2d 613, 225 U.S.P.Q. 634 (Fed. Cir. 1985) (quoting *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136, 118 U.S.P.Q. 122, 132 (2d Cir.)). In view of the foregoing, Applicants submit they have met their burden under 35 U.S.C. 112 second paragraph and respectfully request the rejection to be withdrawn.

### III. 35 U.S.C. § 112 first paragraph

**Claims 1-7 are rejected under 35 U.S.C. § 112 first paragraph as containing new matter as amended in the Response to Restriction Requirement filed October 17, 2002**

The Examiner asserts that claims 1-7 introduce new matter in their recitation of nucleic acid fragments from about 30 to about 300 nucleotides in length. Further, the Examiner asserts that the disclosure only describes fragments of 30 to about 300 nucleotides as a target for computer based searching. Applicants respectfully disagree. The purpose of the written description requirement is simply to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *See Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. The statement on page 82 of the disclosure, which is not limited to computer based methods, indicates that a sequence length of a target sequence can be about 30 to 300 nucleotides. Target sequences are discussed not only in regard to computer based searching embodiments, but are discussed throughout the disclosure in relation to nucleic acids and fragments thereof. For example at page 50, lines 12-18, the specification discloses the use of OLA to amplify a target sequence present in a nucleic acid, and at page 55 the specification discloses "An array consisting of oligonucleotides or cDNA molecules complementary to a subsequence of a target sequence. . . ." In view of the foregoing, Applicants have met the requirements of 112 first paragraph as a person of ordinary skill in the art would,

after reading the specification, understand that the inventors had possession of the claimed invention. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584.

**Claims 1-7 are rejected under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph, Written Description**

Claims 1-7 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. Applicants thank the Examiner for indicating that claims limited to the sequence of SEQ ID No. 1 would meet the written description and enablement requirement of 35 U.S.C. § 112 first paragraph.<sup>1</sup> Applicants respectfully direct the Examiner's attention to new submitted claims 16-22.

Applicants respectfully traverse the rejection of claims 1-7 under 112 first paragraph. The purpose of the written description requirement is simply to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *See Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989).

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<sup>1</sup> Applicants note that the Examiner has referred to the disclosure of SEQ ID NO: 1. on page 5 of the Office Action, however, as SEQ ID NO. 2 is the elected invention.

A related and equally well-established principle of patent law is that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston Purina Co. v. Far-Mar-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (quoting *In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA. 1981)). Thus, simply because the claimed nucleic acid sequences may also include other sequences does not require that Applicants describe each and every one of these molecules. Further, “a description as filed is presumed to be adequate, unless and until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption.” *Federal Register* 66(4):1107, Written Description Guidelines (2001). In this regard, the Examiner is required to disclose “express findings of fact which support the lack of written description conclusion.” *Id.*

Applicants have provided detailed chemical structures of the claimed nucleic acid sequences. These sequences provide “structural feature[s] possessed by members of the [claimed] genus that distinguish[es] them from others.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). In contrast to the mere name “cDNA” provided in *Eli Lilly*, Applicants have provided detailed chemical structures. For at least this reason, it is respectfully submitted that the present claims meet the written description provision under 35 U.S.C. § 112, 1<sup>st</sup> paragraph.

The use of open claiming language (comprising) does not alter the fact that a skilled artisan would readily envision adequate written description support. The fact that nucleic acid sequences may be added to either end of the recited sequence is beside the point. Applicants have therefore reasonably conveyed to one skilled in the art possession of the claimed invention, even when additional sequences are added to either end. Indeed, as set forth in the original disclosure, the additional of extra nucleotides encoding, for example, bacterial ORI sequence or

promoters are readily envisioned by those of ordinary skill upon reading the present specification.

Accordingly, for at least the foregoing reasons, the rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, written description, is traversed, and withdrawal of this rejection is respectfully requested.

#### **IV. 35 U.S.C. §§ 101 utility and 112 first paragraph use**

**Claims 1-7 are rejected under 35 U.S.C. § 101 as allegedly not being supported by a specific and/or substantial utility, or a well-established utility.**

Claims 1-7 stand rejected under 35 U.S.C. § 101 for allegedly not being supported by either specific and/or substantial utility, or a well-established utility.<sup>2</sup> In addition, the Examiner asserts that further characterization of the claimed subject matter would be required to identify or reasonably confirm a “real world” use. Office action dated January 10, 2002, at pages 9-11.

It is well-established that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention, a number of which are outlined under the heading “Uses of the Agents of the Invention” beginning on page 35 of the disclosure. The disclosed uses include, but are not limited to, employing the claimed nucleic acids as genetic markers for Quantitative Trait Loci mapping (see page 40), characterize transformants or germplasm, as a genetic diagnostic test for plant breeding or to identify individuals or varieties,

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<sup>2</sup> Applicants note the Examiner asserts the invention is drawn to nucleic acids comprising a 50 - 100 nucleotide fragment of SEQ ID NO. 1, and that such nucleic acids are capable of hybridizing to a nucleic acid having SEQ ID NO. 2, at page 9 of the Office Action. Applicants further note the claims under examination are directed nucleic acids comprising a fragment from about 30 to about 300 nucleotides residues of SEQ ID NO. 2.

(see page 41 at lines 15-20). An Examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). “More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion.” Federal Register 66(4):1096, Utility Guidelines (2001). “[A] ‘rigorous correlation’ need not be shown in order to establish practical utility; ‘reasonable correlation’ is sufficient.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996). As such, an Examiner “must do more than question operability – [the examiner] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (CCPA 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1). No such factual reasons have been provided. Thus, the utilities disclosed by Applicants must be accepted as factually sound unless and until the Patent Office provides factual reasons that undermine the credibility of the assertion. Therefore, the Office has not met the requisite burden to impose a 35 U.S.C. § 101 rejection.

In sum, Applicants have asserted substantial, specific utilities for the claimed nucleic acid molecules of the invention, and absent specific evidence to the contrary, this assertion must be accepted. As such, Applicants have met their burden in establishing specific, “real-world” utilities for the claimed invention. In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by specific and well-established utilities as disclosed in the

specification. As such, withdrawal of this rejection is respectfully requested.

**Claims 1-7 are rejected under 35 U.S.C. § 112 first paragraph as allegedly not being supported by a patentable use.**

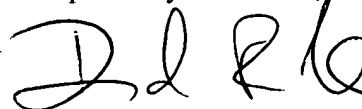
Applicants respectfully disagree with the Examiner's allegation that Claims 1-7 are not supported by a patentable use for the reasons set forth in the corresponding rejection under 35 U.S.C. 101. Applicants contend that the claimed invention is supported by a patentable utility and as such request respectfully request withdrawal of this rejection.

### **Conclusion**

In view of the above, each of the presently pending claims in the application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested in withdraw the outstanding rejections of the claims and to pass this application to issues. The Examiner is invited to contact the undersigned at (202) 942-5000 with respect to any unresolved issues remaining in this application.

The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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Date: April 10, 2002


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**MARKED-UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. 121**

**IN THE SPECIFICATION:**

Please replace the paragraph at page 1 lines 17 – 27 with the following paragraph:



Sequence tagged connectors, or STCs, are sequences of insert data generated from both ends (at the vector-insert point) of a BAC clone in a genomic library. These sequences, and BACs containing these STC sequences, can be used, for example, for marker development, genetic mapping or linkage analysis, marker assisted breeding, and physical genome mapping (Venter, *et al.*, *Nature*, 381:364-366 (1996), the entirety of which is herein incorporated by reference; Choi and Wing, [[http://www.](http://www.genome.clemson.edu/protocols2-nj.html)] on the world wide web at genome.clemson.edu/protocols2-nj.html July, 1998). STCs can represent a copy of up to a full length of a mRNA transcript, a promoter element or part of a promoter, can contain simple sequence repeats (also called microsatellites) repetitive elements or fragments of repetitive elements, other DNA markers, or any combination thereof. –

Please replace the paragraph at page 4 lines 15 – 24 with the following paragraph:

-- Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) [[\(http://www.ddbj.nig.ac.jp/\)](http://www.ddbj.nig.ac.jp/)] on the world wide web at ddbj.nig.ac.jp; Genbank [<http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html>] on the world wide web at ncbi.nlm.nih.gov/web/Genbank/Index.html; and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) [[http://www.ebi.ac.uk/ebi\\_docs/embl\\_db.html](http://www.ebi.ac.uk/ebi_docs/embl_db.html)] on the world wide web at ebi.ac.uk/ebi\_docs/embl\_db.html. A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries

(BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, 12:76-80 (1994); Birren, *et al.*, *Genome Analysis*, 1:543-559 (1997)).--

Please replace the paragraph at page 29 lines 13 – 24 with the following paragraph:

-- Genomic sequences can be screened for the presence of protein homologues or genes utilizing one or a number of different search algorithms have that been developed, one example of which are the suite of programs referred to as BLAST programs. Other examples of suitable programs that can be utilized are known in the art, several of which are described above in the Background and under the section titled "Uses of the Agents of the Invention." In addition, unidentified reading frames may be screened for protein coding regions by prediction software such as GenScan, which is located on the world wide web at [http://]gnomic.stanford.edu/GENSCANW.html.—

Please replace the paragraph at page 59, line 26, to page 60, line 7, with the following paragraph:

-- Exogenous genetic material may be transferred into a plant cell by the use of a DNA vector or construct designed for such a purpose. Vectors have been engineered for transformation of large DNA inserts into plant genomes. Vectors have been designed to replicate in both *E. coli* and *A. tumefaciens* and have all of the features required for transferring large inserts of DNA into plant chromosomes (Choi and Wing, on the world wide web at [http://]genome.clemson.edu/protocols2-nj.html July, 1998). ApBACwich system has been developed to achieve site-directed integration of DNA into the genome. A 150 kb cotton BAC DNA is reported to have been transferred into a specific *lox* site in tobacco by biolistic bombardment and *Cre-lox* site specific recombination.--

Please replace the paragraph at page 93, lines 12-18, with the following paragraph:

-- Primers are designed from good quality unique sequences. A public available primer design software program, PRIMER 3, (Cambridge, MA) is used. PRIMER 3 can be accessed though the internet at [genome.wi.mit.edu/cgi-bin/primer/primer3.cgi](http://genome.wi.mit.edu/cgi-bin/primer/primer3.cgi) [(<http://www.genome.wi.mit.edu/cgi-bin/primer/primer3.cgi>)]. Default parameters are used except those for product size and primer size are changed. Product Size is Min: 80, Opt: 100, Max: 120 , while Primer Size is Min: 18, Opt: 22 and Max: 27. Oligos are synthesized by Genosis Biotechnologies, Inc (Houston, Texas).--

**In the claims**

Please enter the following amended claims:

1. (Twice Amended) A substantially purified nucleic acid molecule comprising a fragment from about 30 to about 300 nucleotides residues, wherein said fragment exhibits complete complementarity to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: [1 through SEQ ID NO: 304701 or] 2 and a complement thereof.

4. (Twice Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: [1 through SEQ ID NO: 304701 or] 2 and a complement thereof.